9-3216

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
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September 16, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 37

Craig Reichel
Owner
Reichel Foods, LLC.
3706 Enterprise Drive SW
Rochester, Minnesota 55902

Dear Mr. Reichel:

On April 22, 2003, an inspector from the State of Minnesota Department of Agriculture, under contract with the Food and Drug Administration, conducted an inspection of your facility at 3706 Enterprise Drive Southwest, Rochester, Minnesota. During this inspection, the investigator collected label samples from your firm's Dippin' Stix™ Fresh Apples Fruit Dip, consisting of apple and fruit dip, together with your firm's Dippin Stix™ Dill Dip Fresh Carrots, consisting of carrots and dill dip, in single serve packages. Our review reveals that the Fresh Apples Fruit Dip product is misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101—Food Labeling. Our review also reveals that certain claims on the Dippin' Stix™ Dill Dip Fresh Carrots product are subject to the requirements for new drugs under Sections 201(p) and 505 of the Act. You can find the Act and food labeling regulations through links on FDA's Internet homepage at: http://www.fda.gov.

Your Fresh Apples Fruit Dip product is labeled with Nutrition Facts for the package contents, identified as apples and fruit dip, indicating the entirety of the package is to be consumed in a single serving. As the contents include both apples and dip, the reference amount customarily consumed ("reference amount") for the Fresh Apples Fruit Dip product is the combination of the reference amount of main ingredient (i.e., the apples) plus the reference amount of all minor ingredients (i.e., the dip) [21 CFR 101.12(f)(2)]. Hence, any claims on the product must be supported by nutritional information for the total product and not for a single component only, in conformity with 21 CFR 101.12(g).

Your violations of the Act and the food labeling regulations include the following:

The Dippin Stix™ Fresh Apples Fruit Dip product is misbranded within the meaning of 403(r)(1)(A) of the Act in that the label bears a nutrient content claim but the product does not comply with the regulation which would allow it to bear the claim. When used to describe the level of a nutrient, the term "excellent" is defined by regulation to mean that the product contains 20% of the Recommended Daily Intake (RDI) or Daily Recommended Value (DRV) of the referenced nutrient per reference amount [21 CFR 101.54(b)(1)]. The label of your product states, "Apples have long been known to be an excellent source of dietary fiber...," however, the product is labeled to contain 11% of the DRV for fiber. Additionally, the label does not bear a disclosure statement with regard to fat content, as required by 21 CFR 101.54(d) for certain fiber related claims. Product labels that bear fiber claims and do not meet the definition for "low fat" in 21 CFR 101.62(b)(2) must bear a disclosure statement in immediate proximity to the fiber claim, e.g., "Contains [x amount] of total fat per serving. See nutrition information for fat content."

The Dippin Stix™ Fresh Apples Fruit Dip is also misbranded under Sections 403(r)(1)(B) and 403(r)(3)(A)(i) of the Act because the label bears unauthorized health claims. Although these claims concern substance-disease relationships for which health claims are authorized by regulation, they do not meet the requirements of the authorizing regulation in 21 CFR Part 101, Subpart E. The following are examples of such claims.

The product label bears the claim "Apples have long been known to be an excellent source of dietary fiber, which has been found to reduce cholesterol...." This statement is an unauthorized health claim because, as written, it does not contain all of the elements required in order to make an authorized health claim for fiber-containing fruits and the risk of coronary heart disease under 21 CFR 101.77(c). For example, (1) the claim on your product does not indicate that a diet low in saturated fat and cholesterol and high in fiber-containing fruits, vegetables, and grain products "may" or "might" reduce the risk of heart disease [21 CFR 101.77(c)(2)(i)(A)], and (2) the claim does not indicate that the development of heart disease depends on many factors [21 CFR 101.77(c)(2)(i)(F)]. In addition, (1) the product does not meet the nutrient content requirements for a "low saturated fat" and "low fat" food [21 CFR 101.62], as required by 21 CFR 101.77(c)(2)(ii)(B), and (2) the content of soluble fiber, which must be at least 0.6g, is not declared in the nutrition information [21 CFR 101.77(c)(2)(ii)(C) and (D)].

The product label bears the claim "Apples have long been known to be an excellent source of dietary fiber, which has been found to ...prevent certain types of cancer...." This statement is also an unauthorized health claim because, as written, it does not contain all of the elements required in order to make an

authorized health claim for fiber-containing fruits and cancer under 21 CFR 101.76. For example, (1) the claim on your product does not indicate that a diet low in fat and high in fiber-containing fruits, vegetables, and grain products "may" or "might" reduce the risk of some cancers [21 CFR 101.76(c)(2)(A)] and (2) the claim does not indicate that the development of cancer depends on many factors [101.76(c)(2)(D)]. In addition, the product does not meet the nutrient content requirement for a "low fat" food [21 CFR 101.62], as required by 21 CFR 101.76(c)(2)(ii)(B).

Your Dippin' Stix™ Dill Dip Fresh Carrots product label contains the claim "Vitamin A...prevents night blindness...." This claim is not authorized as a health claim, and is evidence that the product is intended for use as a drug because it is intended for use in preventing a disease, night blindness. Under Section 201(g)(1)(B) of the Act, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease are drugs.

This claim also subjects the product to the requirements for "new drugs," as defined in Section 201(p) of the Act, because there is no evidence that the product is generally recognized as safe and effective for its intended use. Therefore, the product may not legally be marketed in the United States without an approved New Drug Application [Section 505 of the Act]. The product is also misbranded because the labeling fails to bear adequate directions for its intended use in preventing disease [Section 502(f)(1) of the Act].

The above violations are not meant to be an all-inclusive list of deficiencies regarding your products and/or their labels and labeling. Other violations can also subject your firm to legal action. It is your responsibility to ensure that all products manufactured and/or distributed by your firm are in compliance with the Act and its implementing regulations.

You should know that the failure to promptly correct these violations may result in FDA taking enforcement action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court order injunction against further marketing of your Dippin' Stix™ Fresh Apples Fruit Dip and Dippin' Stix™ Dill Dip Fresh Carrots product.

It is necessary for you to take action on these matters now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Tyra S. Wisecup, Compliance Officer, at the above address.

Sincerely,

W. Charles Becoat
Director
Minneapolis District